

(For moderate and high complexity testing)

☐ Check (✓) here if additional space is needed to list all technical personnel. Copy this page and attach continuation sheet(s) to the original form.

Statement or Entities Generally: Whoever, in any manner within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statements or entry, shall be fined not more than \$10,000 or imprisoned not more than five years, or both. (U.S. Code, Title 18, Sec. 1001)

6. SIGNATURE OF LABORATORY DIRECTOR	7. DATE
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INSTRUCTIONS FORM CMS-209

This form will be completed by the laboratory. It will be used by the surveyor to review the qualifications of technical personnel in the laboratory.

Instructions

1. Only one person may be listed as the laboratory director (D).
2. For a moderate complexity laboratory, list the positions of D, CC, TC and TP. For a high complexity laboratory, list the positions of D, CC, TS, GS and TP. For cytology, list D, CC, TS, CT/GS and CT.
3. Do not list individuals that only perform waived testing, no testing, and administrative functions.
4. Use a separate line for individuals performing more than one CLIA position.
5. For 4(a) TC/TS:
When listing those individuals holding technical consultant/technical supervisor (TC/TS) positions, use the following grid to indicate the specialty(ies)/subspecialty(ies) in which they presently function. Record the number corresponding to the specialty/subspecialty in the appropriate column (TC/TS). When an individual functions as a TC/TS in more than one specialty/subspecialty, use a line for each specialty/subspecialty.

GRID:

- | | |
|--------------------------|---------------------------|
| 1. Bacteriology | 10. Clinical Cytogenetics |
| 2. Mycobacteriology | 11. Histocompatibility |
| 3. Mycology | 12. Radiobioassay |
| 4. Parasitology | 13. Histopathology |
| 5. Virology | 14. Oral Pathology |
| 6. Diagnostic Immunology | 15. Cytology |
| 7. Chemistry | 16. Dermatopathology |
| 8. Hematology | 17. Ophthalmic Pathology |
| 9. Immunohematology | |

EXAMPLE

EMPLOYEE NAMES			a.								b.	DATE OF SURVEY _____
			POSITION HELD								M OR H	
LAST NAME	FIRST NAME	MI	D	CC	TC	TS	GS	TP	CT/GS	CT		
Smith	John				1					M		
						4				H		
						6				H		

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Indicate the applicable regulatory citation under which the following individuals are qualified: Each laboratory director, technical consultant, technical supervisor, clinical consultant, general supervisor, cytology supervisor, and those testing personnel and cytotechnologist sampled during the survey process.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0151. Expiration Date: 9/30/2021. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

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